

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/702,104	04 11/04/2003		Gregory B. Altshuler	105090-0129	6794
21125	7590	05/24/2006		EXAMINER	
		NEN & FISH LLP	JOHNSON III, HENRY M		
WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD				ART UNIT	PAPER NUMBER
BOSTON, 1	MA 022	10-2604		3739	

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
Office Action Summan	10/702,104	ALTSHULER ET AL.					
Office Action Summary	Examiner	Art Unit					
	Henry M. Johnson, III	3739					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	I.' nely filed the mailing date of this communication. D (35 U.S.C. § 133).					
Status							
1)⊠ Responsive to communication(s) filed on 30 Ms	Responsive to communication(s) filed on 30 March 2006						
3) Since this application is in condition for allowan		secution as to the merits is					
,—	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Diamonidian of Olaima		•					
Disposition of Claims	•						
4) Claim(s) 1,2,4-8,10-17,19-23 and 56-73 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.							
· <u> </u>	5) Claim(s) is/are allowed.						
7) Claim(s) is/are objected to.	6) Claim(s) 1,2,4-8,10-17,19-23 and 56-73 is/are rejected.						
·	coloction requirement						
8) Claim(s) are subject to restriction and/or	election requirement.						
Application Papers							
9) The specification is objected to by the Examine	r.						
10)⊠ The drawing(s) filed on <u>07 April 2004</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Ex							
,—							
Priority under 35 U.S.C. § 119							
 12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents 		-(d) or (f).					
		on No					
2. Certified copies of the priority documents3. Copies of the certified copies of the prior	• •						
	•	ed in this National Stage					
application from the International Bureau * See the attached detailed Office action for a list of		d					
See the attached detailed Office action for a list of	or the certified copies not receive	u.					
Attachment(s)	_						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)							
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date Notice of Informal Patent Application (PTO-152)							
Paper No(s)/Mail Date <u>020404 012204 11018</u> 5	6) Other:						
S. Potant and Tradamady Office		·					

Application/Control Number: 10/702,104 Page 2

Art Unit: 3739

Response to Arguments

Applicant's arguments filed 3/30/2006 with respect to claims have been considered but are most in view of the new ground(s) of rejection.

Claims 1, 2, 4-8, 10-17, 19-23 and 56-73 are pending.

Information Disclosure Statement

The information disclosure statement filed 2/4/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is rejected, as it is not clear how the skin contacting surface can be a plate that transfers heat from the radiation source and have protuberances and include total internal reflection. No figure appears to support this configuration.

Claim 23 is rejected as indefinite as a phase change material has not been cited.

Claim Rejections - 35 USC § 102

Art Unit: 3739

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15 and 73 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,572,637 to Yamazaki et al. Yamazaki et al. disclose a handheld laser skin treatment device with a laser diode projecting radiation through a cylindrical adjuster that includes a microswitch responsive to adjuster's touching the skin for making the electric power supply to turn on, and responsive to adjuster's leaving the skin for making the electric power supply to turn off (Col. 3, lines 24-27). The cylindrical adjuster is interpreted as a protuberance. The laser diode is mounted on an aluminum or aluminum alloy casting heat sink and a fan is included with the heat sink within the handheld unit (Col. 2, lines 50-60). The handheld unit inherently is integral to the heat removal and any body in contact with the handheld unit would "receive" heat from the unit.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 3739

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1, 2, 4-6, 8, 10-14,19, 20, 22 and 56-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,094,767 to limura in view of U.S. Patent 6,273,884 to Altshuler et al. limura teaches a cleaning apparatus including a light source and light transmitting bristles (abstract), the device may be in a toothbrush configuration for dental hygiene (Col. 11, lines 20-30). The bristles are interpreted as protuberances and would contact tissue in a toothbrush configuration. The light source may emit blue light and UV light (Col. 5, lines 24-26). To provide light to a target, the bristles must be optically coupled to the radiation source and the bristles are capable of applying a compressive force to tissue. The light source may be multiple LEDs (array) mounted below specific bristles (Fig. 11) on a circuit board, the circuit board inherently acting as a heat sink for the mounted LEDs. The entire "toothbrush" is capable of being cooled prior to use. Iimura does not teach a total internal reflecting mechanism. Altshuler et al. teach an apparatus for using optical radiation to treat dermatological problems that includes a light delivery mechanism which normally has total internal reflection so that light or other radiation entering the lens is reflected through the lens, however, when the lens is in contact with the patient's skin, the total internal reflection at the skin-contacting surface is broken due to the change of index of refraction at this surface so that light energy is emitted from the lens into the patient's skin (Col. 16, lines 20-29). Altshuler et al. also discloses the use of multiple diodes as sources for individual optical channels (Col. 15, lines 45-50). The multiple diode sources are interpreted as an array. Altshuler et al. teaches a fluence of 40 W/cm² (Col. 11, line 60) and that CW operation is preferred (Col. 4, line 37). It

Application/Control Number: 10/702,104

Art Unit: 3739

would have been obvious to one skilled in the art to use the total internal reflection within the delivery means and the fluences as taught by Altshuler et al. in the invention of limura to provide radiation to tissue for treatment as the control of stray radiation can be a safety issue motivating a skilled artesian to look to analogous art for guidance.

Regarding claim 56, the bristles are in direct contact with the skin and with the concept of total internal reflection provide all the radiation delivered directly to the skin contacting surface.

Regarding claims 59, 60, 66 and 67, limura discloses the LEDs may be of the same or different wavelengths implying they may be the same or different sources.

Regarding claim 61, the different indexes of refraction are the very principal upon which total internal reflection depends.

Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,094,767 to limura in view of U.S. Patent 6,273,884 to Altshuler et al. as applied to claim 1 above, and further in view of U.S. Patent 5,445,608 to Chen et al. limura and Altshuler et al. are discussed above, but do not teach substance delivery or fluences between 10 mW/cm² and 10 W/cm². Chen et al. teach therapeutic radiation of tissue using fluences of 75 mW/cm² (Col. 2, line 48) and using a device that provides for the delivery of an agent to the treatment site concurrent with radiation (Fig. 16A). It would have been obvious to one skilled in the art to use the agent delivery and fluence as taught by Chen in the invention of limura in view of Altshuler et al. as the fluence is developed based on the intended procedure and the photosensitizer used and are well known to a skilled artesian as would be the various methodologies for delivery of a photosensitizer; i.e. systemic, direct, etc.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,094,767 to limura in view of U.S. Patent 6,273,884 to Altshuler et al. as applied to claim 1 above, and further in view of U.S. Patent 6,572,637 to Yamazaki et al. All are discussed above.

Application/Control Number: 10/702,104 Page 6

Art Unit: 3739

It would have been obvious to one skilled in the art to include the contact detector as taught by Yamazaki et al. in the invention of limura in view of Altshuler et al. as an additional safety against spurious radiation. U.S. Patent 5,133,102 to Sakuma discloses an alternative contact sensor further substantiating the obviousness of such detection in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Henry M. Johnson, III Primary Examiner

Art Unit 3739